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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,829	04/18/2002	Christophe Beclin	34920-PCT-USA 072667.0179	2360
21003	7590	01/06/2005	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,829

Applicant(s)

BECLIN ET AL.

Examiner

Medina A Ibrahim

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,28,29,31-45,47-49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-34 is/are allowed.
- 6) ☒ Claim(s) 23,28-29,31, 35-45, 47-49 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 10/08/04 in reply to the Office action of 04/08/04 has been entered. Claims 23, 28-29, 44-45, 47-49 and 51-52 have been amended. Claims 24-27, 30 and 46 have been cancelled. New claim 53 has been added. Therefore, claims 23, 28-29, 31-45, 47-49, 51-53 are pending and are examined.

This Office action contains NEW GROUNDS OF REJECTIONS not necessitated by Applicant's amendments. Therefore, this action is non-final. The delay in applying these grounds of rejection is regretted.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment to the claims.

New Matter

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 48 recites, "conditions that permit the internalization" of a nucleic acid or expression cassette. However, support for the limitation "internalization of a nucleic acid or expression cassette" cannot be found in the specification or in the claims as originally filed. Pages 25-28 as originally filed do not provide support for the limitation. Therefore, the limitation is considered to be a new matter. Applicant is requested to point to

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support for the limitation in the originally filed disclosure or to delete the New Matter in response to this Office action.

Claim Rejections - 35 USC § 112

Claims 23, 44-45, 47-49, and 52-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 04/08/04. Applicant has not specifically argued this rejection.

Claims 23, 44-45, 49, and 52 are indefinite for failing to recite the specific hybridization and wash conditions for "stringent". The instant specification fails to clearly describe the desired stringent conditions. The specification only defines exemplary conditions comprising low, moderate and high stringent conditions. Because hybridization conditions vary from one laboratory to another, what is stringent for one may not be stringent for another. Therefore, one skilled in the art would know what is encompassed by the claims. Dependent claims 47-48 are included in the rejection.

Claim 48 is indefinite because "the conditions that permit internalization of a nucleic acid" or a host cell is not defined in the specification, therefore what is encompassed by the claim is unknown.

Claims 48 and 49 are indefinite in the recitation of "selecting the host organism transformed with said expression cassette" because there is no previous transformation step recited in the claim. Step (i) merely recites, "contacting" the host organism with the expression cassette. It is suggested that "contacting" be replaced with ---transforming--.

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In addition, it is unclear why the selection step (ii) is necessary even if the plant is transformed in step (i). Appropriate correction is required to more clearly define the metes and bounds of the claim.

Claim 53 is indefinite because it is unclear as to whether the homology is based on a portion or the entire length of the reference sequence.

Claim Rejections - 35 USC § 112

Claims 23, 28-29, 35, 31, 35, 44-49 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid sequence of SEQ ID NO: 1 and 2 encoding SEQ ID NO: 3, expression vectors and a transformed plant comprising said nucleotide sequence, and a process of transforming a plant with said nucleotide sequence, does not reasonably provide enablement for an isolated nucleic acid sequence that hybridizes under stringent conditions to nucleotides 1-695 of SEQ ID NO: 1, or SEQ ID NO: 1 or SEQ ID NO: 2 and encoding a protein essential for post transcriptional inactivation, or nucleic acids having at least 80% homology to SEQ ID NO: 1 and 2 having no known function, an expression cassette/ vector comprising said nucleic acid, and transformation of a host organism with said nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 04/08/04. Applicant's arguments filed 04/08/04 have been considered but are not deemed persuasive.

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Applicant argues that instant claims 23, 28-29, and 45-45 are amended to recite the nucleic acid sequences hybridize under stringent hybridization to reference sequences, and that the nucleic acids encode a protein essential for post-transcriptional inactivation. Applicant also argues that processes of transforming host organisms of the claims with heterologous nucleic acids are well known in the art, and that transformation of both bacteria and plant as well as expression of a nucleic acid of the invention in a plant are directly demonstrated in this application. Therefore, Applicant asserts that claims 23, 28-29, 35, 31, 35, 44-49 and 51-53 are fully enabled by the specification, and argues that no undue experimentation is required. Applicant requests that the rejection be withdrawn (response, p. 10-11).

These arguments are not persuasive because the claimed hybridizing nucleic sequences encoding a protein for post-transcriptional inactivation, and nucleic acids having at least 80% homology having no known function are not supported by an enabling disclosure. The scope of the claims encompasses nucleic acid sequences from any source that hybridize to SEQ ID NO: 1 or 2 under various stringent conditions including various low, moderate and high stringent conditions. Applicant has provided no evidence to support the conclusion that the majority of nucleic acids obtainable under such various stringent conditions by hybridizing to a portion or even full length SEQ ID NO: 1 or 2 will encode a protein having the functional activity of SEQ ID NO: 3.

The state of the prior art teaches unpredictability in the inhibition of expression of specific coding sequence via antisense RNA in transgenic plants, due to the variation in the degree of antisense inhibition which resulted in different transgenic clones (see,

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e.g., BIRD et al, Biology and Genetic Review, vol. 9, pages 220-221 (1991)) and due to the mechanism of inhibition of gene expression by means of antisense mRNA which is not universally effective and is poorly understood (Sandler et al (Plant Molecular Biology, vol. 11, pp. 301-310 (1988), see, e.g., page 301, Abstract; page 302, column 1, top two paragraphs). Napoli et al (The Plant Cell, vol. 2, pp. 279-289, 1990) also teach unpredictability inherent in the co-suppression of genes in transgenic plants (see at least, page 279, Abstract).

With respect to claims 48-49 and 51, while transformation of plant, fungi, yeast or bacteria with a heterologous gene is known, the rejected claims are not directed to the transformation a plant, fungi, yeast or bacterial with SEQ ID NO: 1 or 2. The rejected claims are directed to hybridizing nucleic sequences and portions thereof that are functionally unrelated to SEQ ID NO: 1 or 2, transgenic plant, fungi, bacteria, and yeast comprising said hybridizing sequences, and a process that employs said hybridizing nucleic acid sequences.

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): " It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". The *Genentech* court also held that ["(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to

understand and carry out the invention". Id.

Therefore, for the reasons stated above and in the last Office action, the claimed invention is not enabled throughout the broad scope. The rejection is maintained.

Written Description

Claims 23, 28-29, 35, 31, 35, 44-49 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 04/08/04. Applicant's arguments filed 04/08/04 have been considered but are not deemed persuasive.

Applicant argues that claimed nucleic acids have the common structural feature of hybridizing to a reference sequence under stringent conditions, and that they encode a protein essential for post-transcriptional inactivation (response, p. 12).

This is not persuasive because the stringent hybridization conditions as broadly defined in the specification are not expected to yield nucleic acids that are structurally and functionally related to SEQ ID NO: 1 or 2. Substantial variation in structures and function are expected among nucleic acids that hybridize to the sequence of nucleotide 1-695 of SEQ ID NO: 1, SEQ ID NO: 1, or SEQ ID NO: 2 under various low, moderate and high stringent conditions. Applicant only describes SEQ ID NO: 1 and 2. Therefore, a mere recitation of structure and function in the claims would not provide adequate written description for the nucleic acids as broadly claimed. Therefore, the specification

fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the invention as broadly claimed at the time of filing, as stated in the last Office action.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 29, 44-45, 47-49, 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Moon et al (5, 656, 466). This rejection is based on the language of nucleic acid encoding a portion of the protein in claim 23, and the nucleic acid in the expression cassette of claims 44-45 and 52 that do not recite encoding language, therefore have no known function. The plants transformed with said nucleic acids are indistinguishable from the prior art plants as set forth below. Also, note the 112, 2nd paragraph rejection above regarding the hybridization conditions.

The claims are drawn to an isolated nucleic acid that hybridizes to the sequence of SEQ ID NO: 1 or 2, or the sequence from nucleotides 1-695 of SEQ ID NO: 1, wherein the nucleic acid encodes a portion of a protein essential for post-transcriptional inactivation, a vector and expression cassette comprising said nucleic acid operably linked to a plant promoter and terminator, a plant transformed with said vector or expression cassette, and a process of expressing a heterologous gene in a plant comprising contacting a plant with said nucleic acid or expression cassette, and culturing the transformed plant under conditions that allow expression of said nucleic acid. The claims are also drawn to nucleic acids that selectively hybridize to the complement of SEQ ID NO: 1 or 2.

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Moon et al teach an isolated nucleic acid from a plant encoding a ribosome inactivating protein ribosome, a DNA construct or a vector comprising a plant promoter operably linked to said nucleic acid (Examples 1-3). The cited reference also teaches a method of expressing said nucleic acid in plants, culturing the transformed plant cells, and producing transformed plants expressing the ribosome inactivating protein (Examples 3-4). The claimed nucleic acid and transgenic plants comprising them, and the method are all disclosed by Moon et al. Therefore, Moon et al teach all claim limitations.

Remarks

Claims 32-34 and 53 are free of the prior art because the prior art does not teach or fairly suggest the isolated nucleic acid sequence of SEQ ID NO: 1 or 2 or a nucleic acid having at least 80% homology to SEQ ID NO: 1 or 2.

Claims 32-34 are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

12/16/04

Mai

Medina A. Ibrahim

**MEDINA A. IBRAHIM
PATENT EXAMINER**